



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

**FULTON**

**Serial No.: 10/628,090**

**Filed: July 25, 2003**

**For: BIOPSY LOCALIZATION METHOD  
AND DEVICE**

Group Art Unit: 3736

Examiner: Szmal

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-SB/08a and PTO-SB/08b.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☐ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the

**CERTIFICATE OF MAILING (37 C.F.R. §1.8)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class mail in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

March 21, 2006  
Date of Deposit  
NB1:671521.1

*Cynthia B. Pacheco*  
Cynthia B. Pacheco

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mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

- ☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.
- ☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.
- ☒ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.
- ☒ The fee due under 37 CFR § 1.17(p) is submitted herewith.
- ☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.
- ☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**Statement Under 37 CFR § 1.97(e):**

- ☐ Each item contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

Some references are in a language other than the English language. A concise explanation of relevance is given below (English language abstracts).

**DE 3913935**

A catheter (1), for removing stones from the ureter, is made from flexible plastics with a retractable mandrel (6) which passes through the catheter from one end to the other. The distal end of the

mandrel (6) is attached to a short strip of net-like material (2). A fine wire (5) also passes through the catheter and its distal end is attached to a plastic tip (3) which fits over the pointed end of the net-like strip so that a loop is formed between the wire (5) and the net (2). By pulling on the mandrel (6) the net (5) can be retracted inside the catheter before the catheter is inserted into the ureter. USE - Removal of stones from the ureter.

**DE 4330958**

The invention relates to novel microparticles containing active compound, which, additionally to the active compound(s), contain at least one gas or gaseous phase, media (microparticulate systems) containing these particles, their use for the ultrasonically controlled in vivo release of active compound and process for the production of the particles and media.

**DE 4403789**

The invention relates to the use of coloured NMR, X-ray or possibly dye-containing ultrasonic-image-producing substances for marking bodily tissues.

**DE 935625**

This reference discloses a biopsy instrument and method for acquiring subcutaneous biopsies and for removing lesions.

**FR 2714284**

The prosthesis consists of a circular component made from a supple material with a shape memory effect, able to occupy three different positions. In the first position (2) it is extended lengthwise to form a small cylinder which can be introduced through a catheter, with its proximal end closed by a valve (4). In a second position the two compartments (8,10) are inflated separately so that they are deployed on opposite sides of the ruptured wall, while in the third position the compartments are squeezed together to form a double patch on the wall. The prosthesis has a radio-opaque marker (6) between the two compartments which allows its progress through the patient's body to be monitored.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☐ A check in the amount of \$180.00 is enclosed for the above fee(s).  
☒ Please charge \$180.00 to Deposit Account No. **50-2862** for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to O'Melveny and Myers' Deposit Account No. **50-2862**.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: March 21, 2006

By: Diane Wong  
Diane Wong  
Reg. No. 54,550  
Attorneys for Applicant

DKW/  
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Substitute for form 1449A-PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	6	Attorney Docket No.	032,290-066
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## Complete if Known

Application No.	10/628,090
Filing Date	July 25, 2003
First Named Inventor	Fulton
Art Unit	3736
Examiner Name	Szmal
Attorney Docket No.	032,290-066

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	Document No. Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	us-20010034528	10/2001	Foerster	
	2.	us-20020007130	01/2002	Burbank	
	3.	us-20020016555	02/2002	Ritchard	
	4.	us-20020019640	02/2002	McGuckin, Jr.	
	5.	us-20020035324	03/2002	Sirimanne	
	6.	us-20020107437	08/2002	Sirimanne	
	7.	us-20020193815	12/2002	Foerster	
	8.	us-20040049126	03/2004	Zarins	
	9.	us-20040049269	03/2004	Corbitt	
	10.	us-20040204660	10/2004	Fulton	
	11.	us-20040210160	10/2004	Fulton	
	12.	us-20040267155	12/2004	Fulton	
	13.	us-20050020916	01/2005	MacFarlane	
	14.	us-3,001,522	09/1961	Silverman	
	15.	us-3,194,239	07/1965	Sullivan	
	16.	us-3,823,212	07/1974	Chvapil	
	17.	us-3,976,071	08/1976	Sadek	
	18.	us-3,996,938	12/1976	Clark, III	
	19.	us-4,197,846	04/1980	Bucalo	
	20.	us-4,230,123	10/1980	Hawkins	
	21.	us-4,298,998	11/1981	Naficy	
	22.	us-4,320,201	03/1982	Berg	
	23.	us-4,356,572	11/1982	Guillemin	
	24.	us-4,425,908	01/1984	Simon	
	25.	us-4,608,965	09/1986	Anspach, Jr.	
	26.	us-4,611,594	09/1986	Grayhack	
	27.	us-4,638,802	01/1987	Okada	
	28.	us-4,650,466	03/1987	Luther	

Examiner  
SignatureDate  
Considered

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	2	of	6	Attorney Docket No.	032,290-066
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Art Unit	3736
Examiner Name	Szmal

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	29.	us-4,655,211	04/1987	Sakamoto	
	30.	us-4,682,606	07/1987	Decaprio	
	31.	us-4,744,364	05/1988	Kensey	
	32.	us-4,763,642	08/1988	Horowitz	
	33.	us-4,787,391	11/1988	Elefteriades	
	34.	us-4,789,401	12/1988	Ebinger	
	35.	us-4,832,686	05/1989	Anderson	
	36.	us-4,838,280	06/1989	Haaga	
	37.	us-4,907,589	03/1990	Cosman	
	38.	us-4,970,298	11/1990	Silver	
	39.	us-5,002,548	03/1991	Campbell	
	40.	us-5,030,201	07/1991	Palestrant	
	41.	us-5,085,629	02/1992	Goldberg	
	42.	us-5,100,423	03/1992	Fearnot	
	43.	us-5,102,415	04/1992	Guenther	
	44.	us-5,108,421	04/1992	Fowler	
	45.	us-5,120,802	06/1992	Mares	
	46.	us-5,127,916	07/1992	Spencer	
	47.	us-5,148,813	09/1992	Bucalo	
	48.	us-5,183,463	02/1993	Debbas	
	49.	us-5,183,464	02/1993	Dubrul	
	50.	us-5,192,300	03/1993	Fowler	
	51.	us-5,195,540	03/1993	Shiber	
	52.	us-5,204,382	04/1993	Wallace	
	53.	us-5,207,705	05/1993	Trudell	
	54.	us-5,326,350	07/1994	Li	
	55.	us-5,330,483	07/1994	Heaven	
	56.	us-5,342,283	08/1994	Good	

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Sheet	3	of	6	Attorney Docket No.	032,290-066

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	57.	us-5,415,656	05/1995	Tihon	
	58.	us-5,431,676	07/1995	Dubrul	
	59.	us-5,433,751	07/1995	Christel	
	60.	us-5,454,790	10/1995	Dubrul	
	61.	us-5,469,854	11/1995	Unger	
	62.	us-5,507,813	04/1996	Dowd	
	63.	us-5,514,379	05/1996	Weissleder	
	64.	us-5,571,182	11/1996	Ersek	
	65.	us-5,576,016	11/1996	Amselem	
	66.	us-5,626,611	05/1997	Liu	
	67.	us-5,634,883	06/1997	Chin	
	68.	us-5,643,282	07/1997	Kieturakis	
	69.	us-5,645,566	07/1997	Brenneman	
	70.	us-5,656,297	08/1997	Bernstein	
	71.	us-5,670,161	09/1997	Healy	
	72.	us-5,676,146	10/1997	Scarborough	
	73.	us-5,716,404	02/1988	Vicante	
	74.	us-5,716,404	02/1988	Knapp	
	75.	us-5,735,289	04/1998	Pfeffer	
	76.	us-5,752,974	05/1998	Rhee	
	77.	us-5,792,157	08/1998	Mische	
	78.	us-5,794,626	08/1998	Kieturakis	
	79.	us-5,803,901	09/1998	Chin	
	80.	us-5,827,324	10/1998	Cassell	
	81.	us-5,868,708	02/1999	Hart	
	82.	us-5,869,080	02/1999	McGregor	
	83.	us-5,873,904	02/1999	Ragheb	
	84.	us-5,922,024	07/1999	Janzen	

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		Number-Kind Code <sup>2</sup> (if known)			
	85.	us-5,928,260	07/1999	Chin	
	86.	us-5,941,910	08/1999	Schindler	
	87.	us-5,980,564	11/1999	Stinson	
	88.	us-6,015,541	01/2000	Greff	
	89.	us-6,027,520	02/2000	Tsugita	
	90.	us-6,066,325	05/2000	Wallace	
	91.	us-6,083,522	07/2000	Chu	
	92.	us-6,136,014	10/2000	Sirimanne	
	93.	us-6,162,192	12/2000	Cragg	
	94.	us-6,228,055	05/2001	Foerster	
	95.	us-6,261,241	07/2001	Burbank	
	96.	us-6,271,278 B1	08/2001	Park	
	97.	us-6,277,083	08/2001	Eggers	
	98.	us-6,312,429	11/2001	Burbank	
	99.	us-6,331,166	12/2001	Burbank	
	100.	us-6,340,367	01/2002	Stinson	
	101.	us-6,347,241	02/2002	Burbank	
	102.	us-6,352,682	03/2002	Leavitt	
	103.	us-6,356,782	03/2002	Sirimanne	
	104.	us-6,371,904	04/2002	Sirimanne	
	105.	us-6,589,502	07/2003	Coniglione	
	106.	us-6,605,047	08/2003	Zarins	
	107.	us-6,638,308	10/2003	Corbitt	
	108.	us-6,656,200	12/2003	Li	
	109.	us-6,699,205	03/2004	Fulton	
	110.	us-6,730,042	05/2004	Fulton	
	111.	us-6,749,554	06/2004	Snow	
	112.	us-RE34,936	05/1995	Campbell	

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Sheet	5	of	6	Attorney Docket No.	032,290-066

FOREIGN PATENT DOCUMENTS						
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		Country Code <sup>3</sup>	Number <sup>4</sup> Kind Code (if known)			
	113.	DE	3913935	04/1989		
	114.	DE	4330958	03/1995		
	115.	DE	4403789	08/1995		
	116.	DE	935625	11/1955		
	117.	EP	0255123	02/1988		
	118.	EP	0293605	12/1998		
	119.	EP	0350043	04/1990		
	120.	EP	0534696	03/1993		
	121.	EP	0769281	04/1997		
	122.	EP	0966920	12/1999		
	123.	EP	0983749	03/2000		
	124.	FR	2714284	06/1995		
	125.	GB	2020557	11/1979		
	126.	GB	2132091	07/1984		
	127.	WO	9015576	12/1990		
	128.	WO	9319803	10/1993		
	129.	WO	9520370	01/1995		
	130.	WO	9847430	10/1998		
	131.	EP	0894503	03/1999		
	132.	WO	0012009	03/2000		
	133.	WO	0012010	03/2000		
	134.	WO	0205717	01/2002		

Examiner Signature	Date Considered	
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Substitute for form 1449A-PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application No.	10/628,090
				Filing Date	July 25, 2003
				First Named Inventor	Fulton
				Art Unit	3736
				Examiner Name	Szmal
Sheet	6	of	6	Attorney Docket No.	032,290-066

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	135.	BREASTDOCTOR.COM, "Surgical Treatment of Breast Disease, Making the Diagnosis of Breast Cancer: Non-Palpable Breast Masses," <a href="http://www.breastdoctor.com/breast/surgery/biopsy.htm">http://www.breastdoctor.com/breast/surgery/biopsy.htm</a>	
	136.	BREASTDOCTOR.COM, "Surgical Treatment of Breast Disease: What's New? Diagnosing Breast Cancer: The ABBI Breast Biopsy System," <a href="http://www.breastdoctor.com/breast/surgery/abbi.htm">http://www.breastdoctor.com/breast/surgery/abbi.htm</a>	
	137.	CLARKSON, P.: "Sponge Implants for Flat Breasts," Proceedings of the Royal Society of Medicine, Vol. 53 at 880-881 (1960)	
	138.	DUFRANE, P. et al., "Prebiopsy Localization of Non-Palpable Breast Cancer," Journal Belge de Radiologies, Vol. 73, No. 5, pp. 401-404 (10/01/1990)	
	139.	FOURNIER et al: "Experimental Studies and Preliminary Clinical Trial of Vinorelbine-loaded Polymeric Bioresorbable Implants for the Local Treatment of Solid Tumors", Cancer Research 51, pp. 5384-5391, October 1, 1991	
	140.	GINDE, Rajiv M., and GUPTA, Rakesh K., "In Vitro Chemical Degradation of Poly (Glycolic Acid) Pellets and Fibers," Journal of Applied Polymer Science, Vol. 33, pp. 2411-2429 (1987)	
	141.	HUSSMAN, et al., "Optical Breast Lesion Localization Fiber: Preclinical Testing of a New Device," Radiology (1996) 200:865-866	
	142.	HUSSMAN, et al., "MR Mammographic Localization Work in Progress," Radiology (1993) 189:915-917	
	143.	HOFMANN: "Biodegradable Implants in Traumatology: Review on the State-of-the-Art," Arch Orthop Trauma Surg (1995) 114:123-132	
	144.	HOFMANN et al: "Biodegradable Implants in Orthopaedic Surgery - A Review on the State-of-the-Art," Clinical Materials; Vol. 10, 1992; pp. 75-80	
	145.	PANGMAN, W.J. and WALLACE, R.M.: "The Use of Plastic Prosthesis in Breast Plastic and Other Soft Tissue Surgery," The Western Journal of Surgery, Obstetrics and Gynecology at 508 (August 1955)	

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